



DEPARTMENT OF HEALTH & HUMAN SERVICES

VIA FEDERAL EXPRESS

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Our Reference: 2955480

October 23, 2002

Sukhjeet K. Singh, Chief Executive Officer
California Co-Packers LLC
23682 Clawiter Road
Hayward, California 94545

WARNING LETTER

Dear Mrs. Singh:

We inspected your facility located at 23682 Clawiter Road, Hayward, California on September 16 and 20, 2002, and found that you have serious deviations from the Seafood HACCP regulations (21 C.F.R. Part 123). These deviations, which were brought to your attention, cause your ready-to-eat Salmon Spread, Calamari Salad, and Seafood Salad to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act ("Act"). You may find the Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov. The attached handout gives information on how you can obtain a copy of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001, which is available on-line. We listed the deviations on a Form FDA 483 and discussed them with you at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your reference.

The HACCP deviations were as follows:

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 C.F.R. § 123.6(b). However, your firm does not have a HACCP plan for Salmon Spread, Calamari Salad, and Seafood Salad to control the food safety hazards of pathogen growth and toxin formation, specifically *Clostridium botulinum* toxin formation during the thawing of the smoked salmon ingredient, and allergens.

You must immediately take appropriate steps to correct the violations at your facility. We may initiate regulatory action without further notice if you do not correct the problem. For instance, we may take further action to seize your products or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things that you are doing to correct the deviation. You may wish to include in your response documentation such as copies of your HACCP plans, temperature monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 C.F.R. Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Your response should be directed to: Ms. Erlinda N. Figueroa, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,



Charles D. Moss
Acting District Director
San Francisco District

Enclosures:

Form FDA 483
Handout on Fish & Fisheries Products Hazards & Controls Guidance,
3rd edition, June 2001